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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,216	Applicant(s) PAVCNIK ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,8-18,20 and 22-44 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,8-18,44 and 2240 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 8-18, 20, 22-44 are pending and claims 41-43 are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 3, 8-18, 22-40, and 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US 2002/0116024 A1) in view of DeVries et al. (US 6,342,063 B1).

With regard to **claims 1, 22, and 40**, Goldberg et al. (hereinafter Goldberg) discloses a retrievable filter for filtering solid and semi-solid materials. As shown in Figure 1, the retrievable filter comprises a filter portion (10) and an anchor portion (100). The filter portion further comprises an apical hub (24) and a plurality of divergent legs (14) (Figure 1). The anchor portion produces an outward force and therefore overlaps

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the instantly claimed stent ([0057]). The filter portion and anchor portion are releasably connected ([0045]). However, Goldberg does not disclose a separate locking mechanism that connects the filter portion to the anchoring portion or wherein each filter leg comprises an internal lumen.

DeVries et al. (hereinafter DeVries) discloses a retrievable filter comprised of a filter portion (20) and an anchor portion (30) (Figures 1 and 2). As shown in Figure 3, the connection between the filter portion and anchor portion comprises a releasable interference fit locking mechanism (column 5, lines 1-40). This locking mechanism (40) is separate from the filter and anchor portion and comprises a filter attachment means, the portion that connects to the anchor, and a stent attachment means, the portion that connects to the filter. The filter attachment means and stent attachment means are separate since they each comprise a different interference fit on different sides of the locking mechanism (Figure 3). Additionally, the filter attachment means is secured to the stent attachment means through the remaining middle portion of the locking mechanism.

Goldberg discloses a releasable connection between a filter portion and anchor portion of a retrievable filter. DeVries discloses a releasable locking mechanism also between a filter portion and anchor portion of a retrievable filter. Since the locking mechanism of DeVries is comprised of a material susceptible to electrolytic disintegration/weakening, it is advantageous by allowing for easier manipulation (column 5, lines 24-27). The locking mechanism does not require a mechanical release as that disclosed by Goldberg. Therefore, in view of this advantage, it would have been

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obvious at the time of the invention for Goldberg to utilize the locking mechanism of DeVries to releasably secure the filter portion and anchor portion.

Although Goldberg is also silent regarding the filter legs comprising an internal lumen to form a cannula, DeVries discloses that such is known in the art. As shown in Figure 3, DeVries teaches that hollow filter legs are well known. Additionally, this allows for more support in larger patients. Therefore, it would have been obvious at the time of the invention for the filter legs of Goldberg to also comprise an internal lumen.

With regard to **claim 3**, the anchor portion of Goldberg is configured to engage a wall of a patient's vessel ([0001]).

With regard to **claim 8**, Goldberg further discloses hooks (130a-130c) that provide a retention force (Figure 1; [0058]). Apical hub (24) provides a retrieval force that allows the filter portion to detach from the anchor portion ([0054]).

With regard to **claims 9 and 10**, since the filter portion comprises Nitinol, it is the examiner's position that the filter portion is configured to maintain its structure when detached from the stent (0042]).

With regard to **claims 11-15**, as shown in Figure 6, the filter portion avoids contact with a patient's vessel when placed within the vessel.

With regard to **claims 16 and 17**, it is the examiner's position that the locking mechanism is further configured to avoid contact when placed in a patient's vessel.

With regard to **claim 18**, although Goldberg does not specifically disclose the stent as square, it is the examiner's position that such a change in shape is obvious to one of ordinary skill in the art. At the time the invention was made, it would have been

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an obvious matter of design choice to a person of ordinary skill in the art to modify the shape of the Goldberg stent because Applicant has not disclosed that a square stent provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the cylindrical stent of Goldberg because both filters are able to effectively trap emboli.

With regard to **claim 20**, Goldberg further discloses the anchor portion as comprised of Nitinol, which clearly overlaps the instantly claimed self-expanding ([0055]).

With regard to **claim 23**, as shown in Figure 3 of DeVries the top and bottom of the locking mechanism (40) form a cannula where the interference fit occurs.

With regard to **claims 24-26**, DeVries also discloses the use of sutures, an attachment wire, with the locking mechanism (column 4, lines 59-67). The suture would intrinsically bend to secure the filter portion and anchor portion.

With regard to **claims 27-36**, DeVries does not specifically disclose the locking mechanism comprising a slot and ball, Y-shaped adaptor, or a coil. However, links such as a slot and ball, Y-shaped adaptor, and coils are well known to one of ordinary skill in the art. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the filter. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Therefore, it would have been obvious to one of ordinary skill in the

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art for Goldberg in view of DeVries to utilize a locking mechanism comprising a slot and ball, a Y-shaped adaptor, or a coil where a user can alter the force absent evidence to the contrary.

With regard to **claims 37-39**, Goldberg further discloses a hook (40) attached to the apical hub (24) (Figure 2). The hook is connected to locking ring (38) on the apical hub (Figure 2). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the suture/attachment wire taught by DeVries to extend through a filter leg. This would allow the suture to safely enter the patient without getting caught on obstacles in the patient's anatomy.

With regard to **claim 44**, as shown in Figure 4 of Goldberg, the anchor portion comprises a frame having a plurality of sides interconnected by a series of bends (126). Each bend forms a coil (Figure 4).

Response to Arguments

4. Applicant's arguments with respect to claims 1, 3, 8-18, 2240, and 44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/16/2008
/Amy T Lang/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731